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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V. and ORGANON USA INC., Plaintiffs, v. GLAND PHARMA LIMITED, Defendant.	Civil Action No. 20-2750 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck Sharp & Dohme B.V. ("Merck B.V.") and Organon USA Inc. ("Organon") (together, "Merck"), by their attorneys, bring this complaint against Defendant Gland Pharma Limited ("Gland"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271(e)(2), the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of Gland's submission of

an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import all strengths of a purported generic version of Bridion® (sugammadex) Injection prior to the expiration of U.S. Patent No. RE44,733 ("the '733 patent").

PARTIES

2. Plaintiff Merck Sharp & Dohme B.V. ("Merck B.V.") is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Waarderweg 39, Haarlem, Netherlands 2031 BN. Merck B.V. is an indirect, wholly owned subsidiary of Merck & Co., Inc., a New Jersey corporation, which has its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

3. Plaintiff Organon USA Inc. ("Organon") is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. Organon is a wholly owned subsidiary of Merck & Co., Inc.

4. On information and belief, Defendant Gland Pharma Limited ("Gland") is a corporation organized and existing under the laws of India, with a place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandimaisamma Mandal Medchal-Malkjgiri District, Hyderabad, Telangana, 500043 India. On information and belief, Gland is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market, itself or through its U.S. agents.

5. By a letter dated January 31, 2020 ("Gland Notice Letter"), Gland notified Merck that Gland had submitted to the FDA ANDA No. 214364 ("Gland's ANDA") for purported generic versions of sugammadex injection, 200 mg/2 mL and 500 mg/5 mL ("Gland ANDA

Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Gland ANDA Products in or into the United States, including New Jersey, prior to the expiration of the '733 patent.

6. On information and belief, Gland holds Drug Master File No. 34233 for sugammadex sodium.

JURISDICTION AND VENUE

7. Merck incorporates each of the preceding paragraphs 1–6 as if fully set forth herein.

8. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271, for infringement of the asserted patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Gland is subject to personal jurisdiction in New Jersey because, among other things, Gland itself, and through its U.S. agents, has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Gland itself, and through its U.S. agents, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

10. Gland has committed an act of infringement in this judicial district by filing ANDA No. 214364 with the intent to make, use, sell, offer for sale, and/or import the Gland ANDA Products in or into this judicial district, prior to the expiration of the '733 patent.

11. Gland's website states that Gland is a "global player with presence in about

90 countries in five continents," with "world-class manufacturing facilities accepted by global regulatory agencies including USFDA (USA)…." *See*, About Us, *available at* http://www.glandpharma.com/about.html (last visited March 10, 2020). Gland's website further indicates that, in the United States, it has 53 approved ANDAs, 100 under review, and 71 under development. *See* Business Development, Licensing, *available at*, http://www.glandpharma.com/licensing.html (last visited March 10, 2020).

12. Gland has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Gland ANDA Products, that will be purposefully directed at New Jersey and elsewhere in the United States.

13. On information and belief, Gland has systematic and continuous contacts with New Jersey; has established distribution channels for drug products in New Jersey; regularly and continuously conducts business in New Jersey, including by selling drug products in New Jersey, either directly or indirectly through its U.S. agents; has purposefully availed itself of the privilege of doing business in New Jersey; and derives substantial revenue from the sale of drug products in New Jersey.

14. On information and belief, if Gland's ANDA is approved, Gland will manufacture, market, promote, sell, offer for sale, import, use and/or distribute the Gland ANDA Products within the United States, including in New Jersey, consistent with Gland's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Gland, either directly or indirectly through its U.S. agents, regularly does business in New Jersey, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. On information and belief, Gland's generic pharmaceutical products are used and/or

consumed within and throughout the United States, including in New Jersey. On information and belief, the Gland ANDA Products will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the '733 patent in the event that the Gland ANDA Products are approved before the '733 patent expires.

15. On information and belief, Gland derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and that are manufactured by Gland and/or for which Gland is the named applicant on approved ANDAs. On information and belief, various products for which Gland is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

16. On information and belief, Gland has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g.*, *Chiesi USA Inc. et al. v. Gland Pharma Ltd.*, No. 2:19-cv-18565-MCA-MAH, (D.N.J. Sept. 30, 2019); *Medicure Int'l, Inc. v. Gland Pharma Ltd.*, No. 2:18-cv-16246-KM-MAH (D.N.J. Nov. 16, 2018).

17. Additionally, this Court has personal jurisdiction over Gland because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Merck's claims arise under federal law; (b) Gland is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Gland has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Gland's ANDA, participating in the preparation and submission of DMF No. 34233 to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States,

including in this judicial district, such that this Court's exercise of jurisdiction over Gland satisfies due process.

18. Venue is proper in this Court as to Gland because Gland is a foreign entity who may be sued in any judicial district, including in the District of New Jersey. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

THE PATENT-IN-SUIT

19. Merck B.V. is the owner and assignee of the '733 patent, entitled "6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block" (attached as Exhibit A). Merck B.V. has the right to enforce the '733 patent.

20. The '733 patent was duly and legally issued on January 28, 2014. The '733 patent was a reissue of U.S. Patent No. 6,670,340, which was duly and legally issued on December 30, 2003.

21. The '733 patent includes claims that recite 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, compositions containing 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, methods of using 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, and kits containing 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin.

22. 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin is also referred to as sugammadex.

23. The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") currently lists the expiration of the '733 patent as January 27, 2021. On February 4, 2020, the United States Patent and Trademark Office ("PTO") issued a Notice Of Final Determination on the patent term extension ("PTE") application for the '733 patent, wherein the PTO determined that the '733 patent is eligible for 5 years of PTE (attached as Exhibit B).

Therefore, after the PTE certificate is issued, the expiration of the '733 patent will be January 27, 2026.

THE BRIDION® DRUG PRODUCT

24. Organon is the holder of New Drug Application ("NDA") No. 022225, under which the FDA approved the commercial marketing of Bridion® (sugammadex) Injection ("Bridion®") on December 15, 2015, under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a). Bridion® is approved for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery. Bridion® is distributed in the United States by Merck Sharp and Dohme Corp., a wholly owned subsidiary of Merck & Co., Inc., in 200 mg/2 mL and 500 mg/5 mL strengths in a single-dose vial for bolus injection. A true and correct copy of the current prescribing information for Bridion® is attached as Exhibit C.

25. Bridion® is a first-in-class drug that works differently than prior agents used for the reversal of neuromuscular blockade. The active ingredient in Bridion®, sugammadex, is a modified cyclodextrin that acts by directly encapsulating, binding, and inactivating agents used by healthcare providers to induce neuromuscular blockade in patients undergoing surgery, e.g., rocuronium or vecuronium, to reverse their effects. After intravenous injection, Bridion® distributes through plasma and binds to such neuromuscular blocking agents ("NMBAs") to form a complex. This process reduces the amount of NMBA available to bind to nicotinic cholinergic receptors in the neuromuscular junction, resulting in the reversal of neuromuscular blockade.

26. By this mechanism, Bridion® also avoids several of the side effects associated with prior reversal agents, such as acetylcholinesterase inhibitors. Traditional reversal agents are co-administered with other agents to manage these side effects, but the co-administered agents can cause a number of additional side effects. Moreover, Bridion® is capable of reversing

the complete and prolonged block of neuromuscular function (known as "profound block") that can occur with the administration of NMBAs. Further, intravenous administration of sugammadex results in more rapid recovery from moderate or deep neuromuscular blockade in patients undergoing surgery who received rocuronium or vecuronium, as compared to neostigmine or succinylcholine. Because of at least these unique features, Bridion® has been viewed as a significant advance in the field of anesthesiology.

27. Bridion®, as well as methods of using Bridion®, are covered by one or more claims of the '733 patent. The '733 patent has been listed in connection with NDA No. 022225 in the FDA's Orange Book.

DEFENDANT'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

28. On information and belief, Gland has submitted or caused the submission of Gland's ANDA to the FDA under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Gland ANDA Products, as a purported generic version of Bridion®, prior to the expiration of the '733 patent.

29. On information and belief, the FDA has not yet approved Gland's ANDA.

30. In the Gland Notice Letter, Gland notified Merck of the submission of Gland's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Gland ANDA Products prior to the expiration of the '733 patent.

31. In the Gland Notice Letter, Gland acknowledged that the Reference Listed Drug for Gland's ANDA is Bridion®. Bridion® is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.

32. In the Gland Notice Letter, Gland also notified Merck that, as part of its

ANDA, Gland had filed a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '733 patent.

33. On information and belief, Gland submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '733 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the Gland ANDA Products.

34. In the Gland Notice Letter, Gland stated that the Gland ANDA Products contain sugammadex as an active ingredient.

35. On information and belief, Gland prepared and submitted Gland's ANDA, and intends to further prosecute Gland's ANDA. On information and belief, if the FDA approves Gland's ANDA, Gland will manufacture, offer for sale, or sell the Gland ANDA Products within the United States, or will import the Gland ANDA Products into the United States. On information and belief, if the FDA approves Gland's ANDA, Gland will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the Gland ANDA Products in or into the United States.

36. Merck brings this action within forty-five days of receipt of the Gland Notice Letter. Accordingly, Merck is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I – INFRINGEMENT OF THE '733 PATENT

37. Merck incorporates each of the preceding paragraphs 1–36 as if fully set forth herein.

38. The Gland ANDA Products, and the use of the Gland ANDA Products, are covered by one or more claims of the '733 patent, including at least claim 1 of the '733 patent, because claim 1 of the '733 patent encompasses the sugammadex utilized in the Gland ANDA

Products.

39. In the Gland Notice Letter, Gland did not specifically contest infringement of claims 1-3, 5 and 11-14 of the ’733 patent.

40. Gland’s submission of Gland’s ANDA with a Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Gland ANDA Products in or into the United States before the expiration of the ’733 patent is an act of infringement of the ’733 patent under 35 U.S.C. § 271(e)(2)(A).

41. If approved by the FDA, Gland’s commercial manufacture, use, importation, sale, and/or offer for sale of the Gland ANDA Products in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the ’733 patent under 35 U.S.C. § 271(a)-(c).

42. On information and belief, Gland will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Gland ANDA Products in or into the United States immediately and imminently upon approval of Gland’s ANDA.

43. The commercial manufacture, use, sale, offer for sale, or importation of the Gland ANDA Products in or into the United States would infringe one or more claims of the ’733 patent.

44. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the Gland ANDA Products in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the ’733 patent.

45. On information and belief, upon FDA approval of Gland’s ANDA, Gland

will, through its own actions or through the actions of its agents, market and/or distribute the Gland ANDA Products to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Gland will knowingly and intentionally accompany the Gland ANDA Products with a product label or product insert that will include instructions for using or administering the Gland ANDA Products, which are substantially similar to the instructions in the prescribing information for Bridion®, attached as Exhibit C, and which, if followed, will infringe the '733 patent. Accordingly, Gland will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the Gland ANDA Products to directly infringe the '733 patent. On information and belief, Gland will encourage acts of direct infringement with knowledge of the '733 patent and knowledge that Gland is encouraging infringement.

46. On information and belief, Gland plans and intends to, and will, actively induce infringement of the '733 patent when Gland's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Gland's activities will be done with knowledge of the '733 patent and specific intent to infringe that patent.

47. On information and belief, Gland knows that the Gland ANDA Products and proposed labeling are especially made or adapted for use in infringing the '733 patent, that the Gland ANDA Products are not a staple article or commodity of commerce, and that the Gland ANDA Products and accompanying proposed labeling are not suitable for substantial noninfringing use. On information and belief, Gland plans and intends to, and will, contribute to infringement of the '733 patent immediately and imminently upon approval of Gland's ANDA.

48. Notwithstanding Gland's knowledge of the claims of the '733 patent, Gland has continued to assert its intent to manufacture, use, offer for sale, sell, distribute, and/or import the Gland ANDA Products with its product labeling in or into the United States following FDA

approval of Gland's ANDA prior to the expiration of the '733 patent.

49. The foregoing actions by Gland constitute and/or will constitute direct infringement of the '733 patent; active inducement of infringement by others of the '733 patent; and contribution to the infringement by others of the '733 patent.

50. On information and belief, Gland filed Gland's ANDA with a Paragraph IV Certification without adequate justification for asserting that the '733 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Gland ANDA Products. On information and belief, Gland has acted with full knowledge of the '733 patent and without a reasonable basis for believing that it would not be liable for direct infringement of the '733 patent; active inducement of infringement by others of the '733 patent; and/or contribution to the infringement by others of the '733 patent. On information and belief, the direct and indirect infringement by Gland of the '733 patent was and is willful. Gland's conduct renders this case "exceptional" under 35 U.S.C. § 285.

51. Merck will be substantially and irreparably damaged by infringement of the '733 patent. Unless Gland is enjoined from directly infringing the '733 patent, actively inducing infringement of the '733 patent, and contributing to the infringement of the '733 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law, and considering the balance of hardships between Merck and Gland, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) A judgment that the '733 patent has been infringed under 35 U.S.C. § 271(e)(2) by Gland's submission to the FDA of Gland's ANDA;

(b) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), ordering that the effective date

of any FDA approval of the commercial manufacture, use, or sale of the Gland ANDA Products, or any other drug product that infringes or the use of which infringes the '733 patent, be not earlier than the expiration date of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Gland, and all persons acting in concert with Gland, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Gland ANDA Products, or any other drug product covered by or whose use is covered by the '733 patent, prior to the expiration of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Gland ANDA Products, or any other drug product that is covered by or whose use is covered by the '733 patent, prior to the expiration of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity, will infringe, induce the infringement of, and contribute to the infringement by others of the '733 patent;

(e) A declaration that Gland's commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Gland ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '733 Patent by Gland under one or more of 35 U.S.C. § 271(a), (b), and (c);

(f) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Gland engages in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Gland ANDA Products, or any product that infringes the

’733 patent, or induces or contributes to such conduct, prior to the expiration of the ’733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment that Gland willfully and deliberately infringed the ’733 patent;

(h) A declaration that this is an exceptional case and an award of attorney’s fees pursuant to 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

Dated: March 12, 2020
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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